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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,034	02/08/2002	Joseph Anthony Cornicelli	A0000417-01-CFP	3098
28880	7590	03/26/2004		
WARNER-LAMBERT COMPANY 2800 PLYMOUTH RD ANN ARBOR, MI 48105				
EXAMINER CRIARES, THEODORE J				
ART UNIT		PAPER NUMBER		
1617				

DATE MAILED: 03/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/071,034	Applicant(s) CORNICELLI ET AL.	
	Examiner Theodore J. Criares	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 14 and 16-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, a5 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/01/02</u> . | 6) <input type="checkbox"/> Other: _____  |

## **CLAIMS 1-30 ARE PRESENTED FOR EXAMINATION**

Applicant's election with traverse of Group I in the papers filed 11/28/03 is acknowledged. The traversal is on the ground(s) that the compounds claimed are in fact classified in the same class and subclass. This traversal is found persuasive. The claims were searched for the compounds with respect to the compounds of U.S. Patents 5, 491,172, 5,633,287 and 6,093,744.

The elected compound of claim 4 was searched sulfamic acid [[2,4,6,-tris(1-methylethyl)phenyl]acetyl]-2,6-bis(1-methylethyl)phenyl ester.

Further restriction was required since claims 13 and 14 are drawn to a method of treating the following medical disorders:

1. rheumatoid arthritis;
2. osteoarthritis;
3. psoriasis;
4. asthma;
5. a cardiovascular disease;
6. an acute coronary syndrome;
7. congestive heart failure;
8. Alzheimer's disease;
9. multiple sclerosis
10. cancer;
11. type 2 diabetes;
12. metabolic syndrome X;
13. inflammatory bowel disease;
14. systemic lupus erythematosus;
15. Grave's disease;
16. myasthenia gravis;
17. insulin resistance;
18. autoimmune hemolytic anemia;
19. scleroderma with anticollagen antibodies;
20. pernicious anemia; or
21. diabetes mellitus.

Each invention (specific medical condition) is independent from the other since, for example, the treatment of rheumatoid arthritis is completely different from the treatment of systemic lupus erythematosus. Rheumatoid arthritis is treated with analgesics whereas systemic lupus erythematosus is treated by aggressive therapy including morphine. The separate considerations are not limited to the patent files and would require a search of the literature which would place an undue burden on the examiner. Therefore, restriction for examination purposes is proper.

A telephone interview with Claude F. Purchase, Jr, on March 19, 2004 wherein election was made of rheumatoid arthritis.

A search was made of the compounds set forth above as contained in U.S. Patents 5, 491,172, 5,633,287 and 6,093,744 as the active agents to be administered in the treatment of rheumatoid arthritis.

Therefore claims 1-13. 15 and 30 have been examined and claims 14 and 16-29 have been withdrawn from consideration.

#### **DETAILED ACTION**

##### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants have an O (oxygen) radical attached to nitrogen in the formula set forth at lines 3-8 of claim 2.

Correction is required since this is considered an inadvertent error.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 13 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Bocan (WO 97/16184). The publication date of this WO patent is May 9, 1997 and the Provisional Application date of the subject application is February 12, 2001.

Bocan teaches at page 8, lines 15 –25 and page 1, line 36 to page 3, line 11 applicants' claimed sulfamic acid CC(C)C1=CC=C(C=C1)C(=O)NS(=O)(=O)C2=CC=C(C=C2)C(=O)O -2,6-bis(1-methylethyl)phenyl ester is an ACAT inhibitor and therefore useful in the treatment of hypercholesterolemia and atherosclerosis. The administration of this known compound would inherently treat a disease by the pathways claimed in claims 1 and 30 as set forth in Ex parte Novitski 26 USPQ2d 1389.

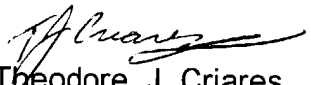
This decision requires that the claims define an invention over the prior art. In the claims under consideration, applicants are administering a known compound which

Claims 3-12 and 15 are rejected since they read on rejected claims 1, 2 and 13.

None of the claims are allowed.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Theodore J. Criares  
Primary Examiner  
Art Unit 1617

TJC  
3/24/04